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Atty. Dkt. No. 076333-0331

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Robert H. GETZENBERG

Title: RENAL NUCLEAR MATRIX PROTEINS, POLYNUCLEOTIDE SEQUENCES ENCODING THEM, AND THEIR USE

Appl. No.: 10/713,149

Filing Date: 11/17/2003

Examiner: Peter J. Reddig

Art Unit: 1642

Confirmation No: 9439

LETTER

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to your telephone request, attached please find a copy of each of the non-US citations listed in the PTO/SB/08 Form submitted March 8, 2004 for the subject application. The reference entitled Matritech, NMP22® Test Kit (6/96) pp. 1-39 is not available at this time. An updated PTO/SB/08 form omitting this citation and dated January 3, 2007 is submitted herewith.

Applicants respectfully request consideration of these references by the examiner.

Receipt of the initial Office Action on the merits is awaited.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date

3 January 2007

By

FOLEY & LARDNER LLP
Customer Number: 22428
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Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: January 3, 2007

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1 of 4

Complete if Known

Application Number	10/713,149
Filing Date	11/17/2003
First Named Inventor	Robert H. GETZENBERG
Group Art Unit	1642
Examiner Name	Peter J. Reddig
Attorney Docket Number	076333-0331

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,882,268		Penman et al.	11/21/89	
	A2	5,273,877		Fey et al.	12/28/93	
	A3	5,849,509		Coffey et al.	12/15/98	
	A4	5,866,535		Getzenberg et al.	2/2/99	
	A5	4,885,236		Penman et al.	12/5/89	
	A6	5,824,490		Coffey et al.	10/20/98	
	A7	5,547,928		Wu et al.	08/20/96	
	A8	6,232,443		Getzenberg	3/1998	
	A9	5,989,826		Beausang et al.	11/23/1999	
	A10	6,162,608		Beausang et al.	12/19/2000	
	A11	6,410,247		Beausang et al.	6/25/2002	
	A12	Re 35,747		Penman et al.	3/17/1998	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A13	WO	95/16919			6/22/95		
	A14	WO	93/09437			5/13/93		
	A15	WO	94/00573			1/6/94		
	A16	WO	87/03910			7/2/87		
	A17	WO	94/18222			8/18/94		
	A18	WO	97/16206			9/5/97		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A19	Miyana, N. et al., "Nuclear Matrix Proteins as a Urine Marker for Transitional Cell Carcinoma of the Bladder", The Journal of Urology Supplement, Vol. 153, No. 4 (XP-002068914)	
	A20	Merrifield S. et al., "The Performance of the NMP22™ Test Kit: A Quantitative Enzyme Immuno-Assay for Bladder Cancer", Tumor Biology, 17 (suppl 1)(1996) (XP-002068915)	
	A21	Getzenberg, R. et al., "Bladder Cancer-associated Nuclear Matrix Proteins", Cancer Research Vol. 56, No. 7, pp. 1690-1694, (1996). (XP-002068894).	
	A22	Konety, B.R., Identification of Nuclear Matrix Protein Alterations Associated with Renal Cell Carcinoma", The Journal of Urology, Vol. 159, No. 4, pp. 1359-1363 (1998). (XP002068895).	

Examiner Signature

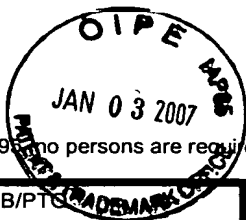
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: January 3, 2007

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Sheet 2 of 4

Complete if Known

Application Number	10/713,149
Filing Date	11/17/2003
First Named Inventor	Robert H. GETZENBERG
Group Art Unit	1642
Examiner Name	Peter J. Reddig
Attorney Docket Number	076333-0331

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	A23	Eberharten A., et al., "Nuclear Matrix of the Lower Eukaryote Physarum Polycephalum and the mammalian epithelial LLC-PKI cell line—A comprehensive investigation of different preparation procedures", Vol. 212, No. 2, pp. 573-580 (1992). (XP02068893).	
	A24	Keese, S.K., et al., "Utilization of Nuclear Matrix Proteins for Cancer Diagnosis", Critical Reviews in Eukaryotic Gene Expression, Vol., 6, No. 2&3, pp. 189-214 (1996). (XP002069158).	
	A25	Getzenberg, R.H., "Nuclear Matrix and the Regulation of Gene Expression: Tissue Specificity", Journal of Cellular Biochemistry, Vol. 55, pp. 22-31 (1994).	
	A26	Getzenberg, R.H. et al., "Identification of Nuclear Matrix Proteins in the Cancer and Normal Rat Prostate", Cancer Research, Vol. 51, pp. 6514-6520 (1994).	
	A27	Berezney, R. et al., "Identification of a Nuclear Protein Matrix", Biochemical and Biophysical Research Communications, Vol. 60, No. 4 (1974).	
	A28	Fey, E.G. et al., "The Nuclear Matrix: Defining Structural and Functional Roles", Eukaryotic Gene Expression, pp. 127-143 (1991).	
	A29	Fey E.G. et al., "Tumor promoters induce a specific morphological signature in the nuclear matrix-intermediate filament scaffold of Madin-Darby canine kidney (MDCK) cell colonies", Proc. Natl. Acad. Sci. USA, vol. 81, pp. 4409-4413 (1984).	
	A30	Fey E.G. et al., "Nuclear matrix proteins reflect cell type of origin in cultural human cells", Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 121-125 (1988).	
	A31	Fey E.G. et al., "Epithelial Cytoskeletal Framework and Nuclear Matrix-Intermediate Filament Scaffold: Three-dimensional Organization and Protein Composition", The Journal of Cell Biology, Vol. 98, pp. 1973-1984 (1984).	
	A32	Weidner, N. et al., "Rapid Communication, Localization of Nuclear Matrix Proteins (NMPs) in Multiple Tissue Types with NM-200.4™ (An Antibody Strongly Reactive with NMPs Found in Breast Carcinoma)", American Journal of Pathology, Vol. 138, No. 6, pp. 1293-1298 (1991).	
	A33	Huse, W.D. et al., "Generation of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda", Research Article, pp. 1275-1281 (1989).	
	A34	Mullinax, R.L. et al., "Identification of human antibody fragment clones specific for tetanus toxoid in a bacteriophage λ immunoexpression library", Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 8095-8099 (1990).	
	A35	Diener E. et al., Specific Immunosuppression by Immunotoxins Containing Daunomycin", Science Vol. 231, pp. 148-150 (1986).	
	A36	Greiner, J.W., "Recombinant Interferon Enhances Monoclonal Antibody –Targeting of Carcinoma Lesions in Vivo", Reports, pp. 895-898 (1987).	
	A37	Wolff B. et al., "The Use of Monoclonal Anti-Thy1IgG1 for the Targeting of Liposomes to AKR-A Cells in Vitro and In Vivo", Biochimica et Biophysica Acta, Vol. 802, pp. 259-273 (1984).	

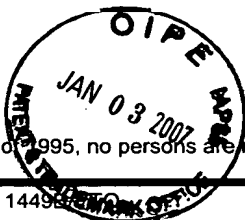
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		Application Number	10/713,149
		Filing Date	11/17/2003
		First Named Inventor	Robert H. GETZENBERG
		Group Art Unit	1642
		Examiner Name	Peter J. Reddig
		Attorney Docket Number	076333-0331

Sheet	3	of	4
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A38	Weintraub H.M. "Antisense RNA and DNA" Scientific American pp. 40-46 (1990).	
	A39	Cech, T.R. Ph.D., Ribozymes and Their Medical Implications", JAMA, Vol. 260, No. 20, pp. 3030-3034 (1988).	
	A40	Haseloff, J. et al. "Simple RNA enzymes with new and highly specific endoribonuclease activities" Nature, Vol. 334, pp. 585-591 (1988).	
	A41	Bejany, D.E. et al., "Malignant Vesical Tumors Following Spinal Cord Injury", The Journal of Urology, Vol. 138, pp. 1390-1392 (1987).	
	A42	Kaufman, J.M. et al. "Bladder Cancer and Squamous Metaplasia in Spinal Cord Injury Patients", pp. 967-971 (1977).	
	A43	Melzak J. M.D., "The Incidence of Bladder Cancer in Paraplegia", Paraplegia, pp. 85-96.	
	A44	Nyquist R.H., M.D. et al., "Mortality and Survival in Traumatic Myelof During Nineteen Years, from 1946 to 1965", Paraplegia, pp. 22-48.	
	A45	El-Masri, W.S., "Bladder Cancer After Spinal Cord Injury", International Medical Society of Paraplegia, pp. 265-270 (1981).	
	A46	Geisler, W.O., et al. "Survival in Traumatic Transverse Myelitis", Paraplegia, Vol. 14, pp. 262-275 (1977).	
	A47	Hackler R.H., "A 25-Year Prospective Mortality Study In the Spinal Cord Injured Patient: Comparison With the Long-Term Living Paraplegic", The Journal of Urology, Vol. 117, pp. 486-488 (1977).	
	A48	Pound, C.R. et al., "Differential Nuclear Matrix Protein (NMP) Patterns In Normal Renal Tissue and Renal Cell Carcinoma (RCC)", 92 nd Annual Meeting of the American Urological Association, New Orleans, LA, USA, (1997) J. of Urol. Vol. 157 (4 suppl.) (1997) (XP-002076374).	
	A49	Konety B.R. et al., "Characteristic Nuclear Matrix Protein Alterations in Renal Cell Carcinoma (RCC)", 92 nd Annual Meeting of the American Urological Association, New Orleans, LA, USA (1997), J. or Urol., Vol. 157 (4 suppl.) (1997) (XP-002076375).	
	A50	Gordon, J.N. et al., "Altered Extracellular Matrices Influence Cellular Processes and Nuclear Matrix Organizations of Overlying Human Bladder Urothelial Cells", Cancer Research, Vol. 53, pp. 4971-4977 (1993).	
	A51	Cupo, J., "Electrophoretic analysis of nuclear matrix proteins and the potential clinical applications", Elsevier Science Publishers B.V., pp. 389-406 (1991).	
	A52	Partin, A.W. et al., "Nuclear Matrix Protein Patterns in Human Benign Prostatic Hyperplasia and Prostate Cancer", Cancer Research, Vol. 53, pp. 744-746 (1993).	

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	A53	Russell, P.J. et al. "Preclinical studies of monoclonal antibodies for intravesical radioimmunotherapy of human bladder cancer", Cell biophysics, Vols. 24/25 pp. 155-61 (1994).	
	A54	Kingsley E.A. et al., "Characterization of the anti-bladder-cancer monoclonal antibody BLCA -8: identification of its antigen as a neutral glycolipid", Cancer Immunology, Immunotherapy, Vol. 41, No. 6, pp. 348-54 (1995) (XP000872998).	
	A55	Fradet Y., "Molecular and Immunologic approaches in the management of bladder cancer", Urologic Clinics of North America, Vol. 18. No. 3, pp. 515-24 (1991) (XP000881253).	
	A56	Replogle-Schwab R. et al., "The utilization of nuclear matrix proteins for cancer diagnosis", Critical Reviews in Eukaryotic Gene Expression, Vol. 6, Nos. 2-3, pp. 103-13 (1996), (XP000881255).	
	A57	Pirtskalaishvili G. et al., "Use of urine-based markers for detection and monitoring of bladder cancer", Techniques in Urology, Vol. 5, No. 4, pp. 179-84 (1999) (XP000881344).	
	A58	J.E. Celis et al, "Expression of the transformation-sensitive protein "cyclin" in normal human epidermal basal cells and simian virus 40-transformed keratinocytes," Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 3128-3132 (1984).	
	A59	J.E. Celis et al., "Intermediate filaments in monkey kidney TC7 cells: Focal centers and interrelationship with other cytoskeletal systems", Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 1117-1121 (1984).	
	A60	R.G. DiScipio et al., "Nucleotide sequence of cDNA and derived amino acid sequence of human complement component C9", Proc. Natl. Acad. Sci. USA, vol. 81, pp. 7298-7302 (1984).	
	A61	R.B. Merrifield, "Solid Phase Peptide Synthesis. I. The synthesis of a Tetrapeptide", J. Am. Chem. Soc., Vol. 85, No. 14, pp. 2149-2154 (1963).	
	A62	Stewart and Young, "Solid Phase Peptide Synthesis" Freeman Publ. 1969, pp. 27-61.	
	A63	J.Y. Douillard et al., "Monoclonal Antibodies Specific Immunotherapy of Gastrointestinal Tumors", Hybridoma, Vol. 5, Suppl. 1 (1986) pp. S139-S149.	
	A64	R. Fraley et al., "New Generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids", Trends Biochem. Sci., Vol. 6, pp. 77-80 (1981).	
	A65	T. Gura, Science, "Systems for Identifying New Drugs Are Often Faulty", Nov. 1997, Vol. 278, pp. 1041-1042.	
	A66	LH Hartwell et al., Science, "Integrating Genetic Approaches into the Discovery of Anticancer Drugs" Nov. 1997, Vol. 278, pp. 1064-1068.	

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